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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,629	01/25/2002	Harry R. Davis	CV01382K	2175

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,629	DAVIS, HARRY R.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47,53-55,57 and 58* is/are pending in the application.

4a) Of the above claim(s) *2-7,12,25-31,46,47,57 and 58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8-11,13-24,32-45 and 53-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed JULY 14, 2004 have been entered. The cancellation of claims 48-52 is acknowledged.

Claims 25-31, 46-47, and 57-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in response filed August 4, 2003.

Claims 2-7, and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in response filed August 4, 2003.

Claims 1, 8-11, 13-24, 32-45, and 53-56 have been examined herein to the extent they read on the elected invention and species.

The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the amendments filed JULY 14, 2004.

The outstanding double patenting rejection is withdrawn in view of the amendments field JULY 14, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Apparently there are structures in claim 10 being missing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by '115.

'115 teaches the method of preventing atherosclerosis employing the compounds recited in claim 8 of the instant application, which encompass the elected species, ezetimibe (See claim 9).

Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by '966.

'966 teaches the method of preventing atherosclerosis employing the compounds recited in claim 8 of the instant application, which encompass the elected species, ezetimibe (See claims 6 and 10).

Response to arguments

Applicant's arguments filed JULY 14, 2004 averring the cited prior art's failure to teach the herein claimed method of reducing plasma tissue sterol levels have been considered, but are not found persuasive. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to reducing the sterol levels with old and well known compounds or compositions. It is now well settled law that administering compounds inherently possessing treating utility anticipates claims directed to such use. Arguments that such use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated sterol-lowering utility, renders such claims anticipated by the prior inherent use. Examiner notes that the claim is directed to a method of administering ezetimibe to a mammal in need thereof.

In the instant case, the mammal in need thereof would be considered anyone who is in need of reducing the risk of atherosclerosis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 8-9, 10-11, 13-24, 32-45, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over '966 in view of Belamarich et al. (Pediatrics, 1990;86(6):977-981).

'966 also teaches the elected compound herein, ezetimibe, with HMG-CoA reductase inhibitors such as simvastatin, useful for reducing cholesterol and the risk of artherosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly, claims 6 and 10). '966 also teaches the dosage of ezetimibe for treating hypercholesterolemia as0.1-30 or 0.1-15 mg/kg

(see col. 21, line 17-19). '966 also teaches the dosage of HMG-CoA reductase inhibitors as 10-80mg daily to 1-1000mg daily depending upon the agents used (See col. 21, lines 27-42).

'966 does not expressly teach the employing of ezetimibe with simvastatin, a HMG-CoA reductase inhibitor, in the dosage herein claimed to treat sitosterolemia.

Belamarich et al. teaches that hypercholesterolemia is one of the manifestation of sitosterolemia (See page 977, col. 2, second to last paragraph). Belamarich et al. also teaches cholestyramine and low-sterol diet as effective in lowering the both cholesterol and sterol levels in sitosterolemic pateints (See page 979, col. 2, last paragraph bridging page 980, col. 1, first full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ ezetimibe with simvastatin and/or cholestyramine, in the dosage herein claimed to treat sitosterolemia.

One of ordinary skill in the art would have been motivated to employ ezetimibe with simvastatin and/or cholestyramine, in the dosage herein claimed to treat sitosterolemia. '966 teaches the combination of simvastatin and ezetimibe as useful in reducing cholesterol level. Employing the combination of simvastatin and ezetimibe in a method to reduce cholesterol level and thereby treating sitosterolemia, a condition known to have elevated cholesterol level, would have been reasonably expected to be effective, absent evidence to the contrary. Moreover, cholestyramine is known to be effective in lowering cholesterol in sitosterolemic patient. Therefore, administering all three

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1617